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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,324	04/25/2001	Jeffrey M. Staub	15869/01	8784

27161 7590 08/11/2003

MONSANTO COMPANY
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ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)
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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

15

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,324

Applicant(s)

STAUB ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 13-14, 16 and 18 have been amended as requested in Paper No. 13, filed 28 April 2003.
2. This application contains claims 1-12 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. Claims 1-12 are withdrawn from consideration as being drawn to non-elected inventions. Claims 13-22 are examined.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

5. The objection to claims 16 and 18 because of informalities is WITHDRAWN in light of amendment to the claims.
6. The rejection of claims 13-22 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is WITHDRAWN in light of amendment to the claims.

Response to Arguments

7. Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the

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reasons of record as set forth in the Office action mailed 21 October 20002. Applicant's arguments filed 8 April 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to address potential indefiniteness (response pg 3). This is not found persuasive because the following are new or were not addressed in the amendments:

Claim 13 is indefinite in its recitation of "said protein providing tolerance for a period of time" in part (b). It is believed that the phrase starting with "for a period of time" is not intended to modify "tolerance" or "protein". It is suggested that "for ... replicate" be inserted after "placed".

In claim 14 it remains unclear if proteins are inhibitors of plastid metabolic pathways, proteases or nucleases themselves or if they provide tolerance to inhibitors of plastid metabolic pathways, proteases or nucleases.

Claim 15 remains indefinite in its recitation of "encodes for proteins...." The use of the plural for proteins implies that the nucleic acid sequence encodes more than one protein.

However, parent claim 13, in part (a) states that the nucleic acid sequence encodes a protein.

Claim Rejections - 35 USC § 102

8. The rejection of claims 13-14 and 16-22 under 35 U.S.C. 102(b) as being anticipated by Blowers et al (WO 99/05265) is WITHDRAWN in light of Applicant's arguments that the 1 mM glyphosate used by Blowers et al is lethal.

9. The rejection of claims 13-22 under 35 U.S.C. 103(a) as being unpatentable over Blowers et al (WO 99/05265) in view of Daniell et al (1998, Nature Biotechnol. 16:345-348) is

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WITHDRAWN in light of Applicant's arguments that the 1 mM glyphosate used by Blowers et al is lethal.

Claim Rejections - 35 USC § 112

10. Claims 13-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transforming plastids with a construct comprising a plastid promoter, a nucleic acid comprising the EPSPS coding sequence, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of glyphosate, then after a period of time is selected on a higher concentration, does not reasonably provide enablement for a method of transforming plastids with a construct comprising a plastid promoter, any nucleic acid that encodes a protein that provides tolerance to a plastid lethal compound, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of any plastid lethal compound, then after a period of time is selected on higher concentrations of any plastid lethal compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 October 20002. Applicant's arguments filed 8 April 2003 have been fully considered but they are not persuasive.

Applicant urges that they have provided ample guidance and that Examiner has ignored pg 7-20 of the specification to focus only on the examples, which are only one aspect of the guidance. Applicant thus urges that a *prima facie* case for enablement cannot be established.

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Applicant urges that one of ordinary skill in the art would know which experiments to conduct to practice the methods and make the plants of the instant invention (response pg 4-5).

This is not found persuasive. Neither pages 7-20 of the specification, nor the examples teach genes encoding inhibitors of plastid metabolic pathways, proteases, or nucleases that can be used in the instant method. The only plastid lethal compounds taught are herbicides (e.g., pg 7, lines 26-28). Thus, the specification is not enabled for use of other kinds of plastid nonlethal compounds.

Applicant questions examiner's disclosure regarding phosphinothricin, and states that while direct selection does not work, that is not the claimed invention. Applicant questions whether Examiner understands the invention, which is first culturing in a sublethal amount of a plastid lethal compound followed by a selection step in a lethal amount (response pg 5).

This is not found persuasive because the instant method is one of direct selection, wherein the transformed plant cell is first selected on low concentration of the compound, then after a period of time is selected on a higher concentration of that same compound. Pg 30-32 of the specification is drawn to the non-elected method, wherein the transformed plant cell is first selected on a plastid non-lethal compound, then after a period of time is selected on the lethal compound. Even using that method a low percentage of lines were obtained. The statements by Applicant and Lutz et al regarding direct selection with phosphinothricin bring enablement of the instant selection method into question. Applicant, however, is invited to submit a Declaration showing data that demonstrates that the instant method works with phosphinothricin.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.
August 4, 2003

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**